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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,196	04/14/2004	T. Douglas Mast	END5312USNP	5885

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EXAMINER	
JOHNSON III, HENRY M	
ART UNIT	**PAPER NUMBER**
3769	

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03/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,196	MAST ET AL.	
	Examiner	Art Unit	
	HENRY M. JOHNSON III	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *100708 102908 123108 020209*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed December 3, 2008 have been fully considered but they are not persuasive. Watkin et al., Hill et al. and Billard et al. all provide important disclosures regarding the effect of blood perfusion on ultrasonic ablation of tissue. Contrary to the Applicant's assertion, Hill et al. provide a clear teaching of the use of in vitro data for in vivo ablation as follows:

> An apparent value of the model arises from the fact that well documented lesion size data are considerably more abundant and readily obtained for excised than for living, perfused tissues, and it will probably always be necessary to make some use of the former data base and the above theoretical structure in extrapolating to in vivo human and animal situations. Some caution as to the validity of the model for such extrapolation from excised to living tissue will need to be exercised here, however.

A skilled artisan, by virtue of many years of formal education, likely augmented by research or intern experience, would most assuredly consider this important variable in using experimental in vitro data to develop in vivo procedures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,413,550 to Castel in view of Watkin et al., Hill et al. and Billard et al. (all Non-patent literature).

Castel discloses an ultrasound medical treatment system comprising: a) an ultrasound medical-treatment transducer (unit 2 and element 15); and b) a controller (4) which powers the transducer to deliver ultrasound at an ultrasound acoustic power for or beyond a determined treatment time to thermally ablate patient tissue (column 7 line 66- column 8 line 3), and at or above a determined ultrasound acoustic power for a treatment time to thermally ablate patient tissue (column 9 lines 47-48), wherein the controller determines the treatment time from a function (column 9 lines 29-45). Castel does not disclose determining an in vivo treatment time (or ultrasound acoustic power) from a function of experimentally determined in vitro treatment time (or ultrasound acoustic power) for the transducer to deliver ultrasound at the ultrasound acoustic power (or for the treatment time) for the in vitro treatment time (or at the in vitro ultrasound acoustic power) to thermally ablate patient tissue in vitro. Castel also does not disclose that the mathematical function includes blood perfusion rate and patient tissue density. Watkin teaches conducting studies on in vitro samples to define suitable exposure parameters for a high intensity focused ultrasound procedure in vivo (abstract). Watkin teaches that a

threshold exposure time was determined in vitro (page 193, "In Vitro Tissue Model"), and then the in vivo focal peak intensity was calculated in order to account for the acoustic loss in vivo (page 193, column 2, second full paragraph). Watkin further teaches that for exposure times of greater than approximately 3 seconds, blood perfusion rate and patient tissue density are critical for determining in vivo exposure parameters from in vitro exposure parameters (Discussion, pages 194 and 195). Hill teaches theoretical models of the formation of ultrasonic focal lesions in tissue. The theoretical models include equations with the following variables/terms: time, patient tissue density, blood perfusion rate, temperature, and ultrasonic power deposition rate (page 260). Billard et al. disclose research to determine the effects of blood perfusion rates and tissue properties on ultrasonic pulses to obtain predictable thermal dosages. Billard et al. teach that for short treatment pulses or times, the blood perfusion rate has little impact on the dosages. This clearly teaches that above two second pulse lengths, the blood perfusion rate is significant and a skilled artisan would be motivated to include such in any algorithms for control of the ultrasonic device. The examiner takes the position that the combined teachings of Watkin et al., Hill et al. and Billard et al. provide teachings that a skilled artisan could not ignore in providing models for ultrasonic ablation to in vivo tissue. The prior work in correlating in vitro to in vivo ablation and the effects of both blood perfusion rates and tissue properties would be well known to one of skill in the art. It is also noted that the migration of an experimental laboratory procedure to a practical in vivo procedure is the cornerstone for most medical advances. Castel merely provides a platform or structure for the implementation of the calculated treatments. Therefore, it would have been obvious to one skilled in the art to use a mathematical formula including blood perfusion rate and tissue density as taught by Watkin/Hill/Billard in the invention of Castel to provide in vivo ultrasonic ablation as derived from in vitro experiments, as it is

pervasive in the arts that in vitro procedures evolve to produce in vitro procedures based of the type of research as exemplified by Watkin/Hill/Billard.

Regarding claims 11 and 13, the times are related to intended use with no impact on the device structure.

Regarding claims 12 and 14, 55 seconds is clearly well above the times of two and three seconds as taught by the prior art as being insignificant for blood perfusion and tissue density and therefore a skilled artisan must include such variable in any treatment above three seconds.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to HENRY M. JOHNSON III at telephone number (571)272-4768.

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

/HMJ/

3/8/2009